

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Toshihide Kobayashi et al.

Group Art Unit : 1655

Appl. No. : 10/516,072
(U.S. National Stage of PCT/JP03/06841)

Examiner : Martin

I.A. Filed : May 30, 2003

Confirmation No. : 9668



For : CHOLESTEROL DETECTION REAGENT

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop Amendment
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

In accordance with the duty of disclosure under 37 C.F.R. 1.56, 1.97, and 1.98, Applicants hereby brings the following information to the attention of the Examiner, which includes information cited and discussed in the specification, the International Search Report, and the International Preliminary Examination Report issued in connection with counterpart International Application No. PCT/JP03/06841. Copies of the International Search Report (in English and Japanese), and the International Preliminary Examination Report (in Japanese) were enclosed with the papers when entering the National Stage on November 29, 2004. The Examiner is invited to review these materials to inspect the relevance indicated during international examination with respect to the documents cited therein.

RECEIVED & RECORDED
DATE: 12/18/06

- 1) L.F. AMOROSA et al., "The Effects of Polyoxyethylated Cholesterol Feeding on Hepatic Cholesterol Synthesis and Intestinal Cholesterol Absorption in Rats", *Atherosclerosis*, Vol. 64, pp. 117-123 (1987);
- 2) Hideki ISHIWATA et al., "Physical-Chemistry Characteristics and Biodistribution of Poly(ethylene glycol)-Coated Liposomes Using Poly(oxyethylene) Cholesteryl Ether", *Chem. Pharm. Bull.*, Vol. 43, No. 6, pp1005-1011 (1995);
- 3) JP 8-131197, accompanied by an English language abstract, and English language family member U.S. Patent No. 5,691,159;
- 4) Mark S. BRETSCHER et al., "Cholesterol and the Golgi Apparatus", *Science*, Vol. 261, pp. 1280-1281 (1993), which is cited in the specification beginning on page 1, second paragraph;
- 5) Anton RIETVELD et al., "The Differential Miscibility of Lipids as the Basis for the Formation of Functional Membrane Rafts", *Biochimica et Biophysica Acta*, Vol. 1376, pp. 467-479 (1998), which is cited in the specification beginning on page 1, second paragraph;
- 6) Rhoderick E. BROWN et al., "Sphingolipid Organization in Biomembranes: What Physical Studies of Model Membranes Reveal", *Journal of Cell Science*, Vol. 111, pp. 1-9 (1998), which is cited in the specification beginning on page 1, second paragraph;
- 7) Teymuras V. KURZCHALIA et al., "Membrane Microdomains and Caveolae", *Curr. Opin. Cell. Biol.*, Vol. 11, pp. 424-431 (1999), which is cited in the specification beginning on page 1, second paragraph;

- 8) Elina IKONEN et al., "Caveolins and Cellular Cholesterol Balance", *Traffic*, Vol. 1, pp. 212-217 (2000), which is cited in the specification beginning on page 1, second paragraph;
- 9) D.A. BROWN et al., "Functions of Lipid Rafts in Biological Membranes", *Annu. Rev. Cell Dev. Biol.*, Vol. 14, pp. 111-136 (1998), which is cited in the specification beginning on page 1, second paragraph;
- 10) Kai SIMONS et al., "Lipid Rafts and Signal Transduction", *Nature Reviews: Molecular Cell Biology*", Vol. 1, pp. 31-41 (2000), which is cited in the specification beginning on page 1, second paragraph;
- 11) Linda J. PIKE et al., "Cholesterol Depletion Delocalizes Phosphatidylinositol Bisphosphate and Inhibits Hormone-Stimulated Phosphatidylinositol Turnover", *The Journal of Biological Chemistry*, Vol. 273, No. 35, pp. 22298-22304 (1998), which is cited in the specification beginning on page 1, second paragraph;
- 12) PRALLE et al., "Sphingolipid-Cholesterol Rafts Diffuse as Small Entities in the Plasma Membrane of Mammalian Cells", *The Journal of Cell Biology*, Vol. 148, No. 5, pp. 997-1007 (2000), which is cited in the specification beginning on page 1, second paragraph;
- 13) Katja RÖPER et al., "Retention of Prominin in Microvilli Reveals Distinct Cholesterol-Based Lipid Microdomains in the Apical Plasma Membrane", *Nature Cell Biology*, Vol. 2, pp. 582-592 (2000), which is cited in the specification beginning on page 1, second paragraph;
- 14) Michael S. BROWN et al., "A Proteolytic Pathway that Controls the Cholesterol Content of Membranes, Cells, and Blood", *Proc. Natl. Acad. Sci. USA*, Vol. 96,

- pp. 11041-11048 (1999), which is cited in the specification beginning on page 2, line 2;
- 15) Kai SIMONS et al., "How Cells Handle Cholesterol", *Science*, Vol. 290, pp. 1721-1726 (2000), which is cited in the specification beginning on page 2, line 2;
- 16) Yiannis A. IOANNOU, "Multidrug Permeases and Subcellular Cholesterol Transport", *Nature Reviews: Molecular Cell Biology*, Vol. 2, pp. 657-668 (2001), which is cited in the specification beginning on page 2, line 3;
- 17) Peter G. PENTCHEV et al., "The Niemann-Pick C Lesion and its Relationship to the Intracellular Distribution and Utilization of LDL Cholesterol", *Biochimica et Biophysica Acta*, Vol. 1225, pp. 235-243 (1994), which is cited in the specification beginning on page 2, line 5;
- 18) Laura LISCUM, "Niemann-Pick Type C Mutations Cause Lipid Traffic Jam", *Traffic*, Vol. 1, pp. 218-225 (2000), which is cited in the specification beginning on page 2, line 6;
- 19) Toshihide KOBAYASHI et al., "Late Endosomal Membranes Rich in Lysobisphosphatidic Acid Regulate Cholesterol Transport", *Nature Cell Biology*, Vol. 1, pp. 113-118 (1999), which is cited in the specification beginning on page 2, line 8;
- 20) Hideki ISHIWATA et al., "Cholesterol Derivative of Poly(ethylene glycol) Inhibits Clathrin-Independent, but not Clathrin-Dependent Endocytosis", *Biochimica et Biophysica Acta*, Vol. 1359, pp. 123-135 (1997), which is cited in the specification beginning on page 2, first full paragraph; and

21) Takeshi BABA et al., "Clathrin-Dependent and Clathrin-Independent Endocytosis are Differently Sensitive to Insertion of Poly (Ethylene Glycol)-Derivatized Cholesterol in the Plasma Membrane", Traffic, Vol. 2, pp. 501-512 (2001), which is cited in the specification beginning on page 2, first full paragraph.

In accordance with 37 C.F.R 1.98, a copy of the U.S. Patent is not enclosed herewith. Moreover, Applicants note that copies of the documents cited in the International Search Report should have been forwarded by the International Bureau. Therefore, copies of all of these documents are not being submitted herewith. The Examiner is accordingly requested to consider each of these documents, and to make them of record in this application by initialing in the appropriate spaces on the attached Form-1449. Applicants respectfully request that the Examiner include a copy of the initialed Form PTO-1449 with the next communication from the U.S. Patent and Trademark Office. If the Examiner needs copies of any of the documents, the Examiner is requested to contact the undersigned.

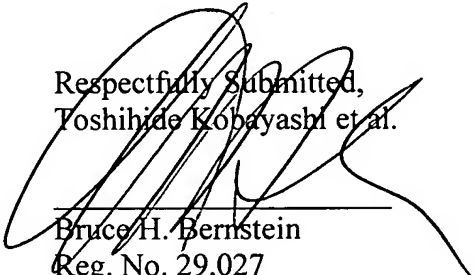
Copies of the above-noted documents, except for the U.S. patent, items 1, 2, and 20 (cited in the International Search Report), are enclosed together with a duly completed Form PTO-1449. The Examiner is accordingly requested to consider each of these documents, and to make them of record in this application by initialing in the appropriate spaces on the Form PTO-1449. Applicants respectfully request that the Examiner include a copy of the initialed Form PTO-1449 with the next communication from the U.S. Patent and Trademark Office.

Applicants note that this disclosure statement is being filed after first action on the merits, but prior to issuance of an office action closing prosecution. Therefore, payment

in the amount of \$180.00 is submitted herewith. However, if the fee is deficient and/or if any additional fee is required for consideration of this disclosure statement, including any fee under 37 C.F.R. 1.17(p), Applicants hereby authorize that any required fee be charged to Deposit Account No. 19-0089.

Should there be any questions, the Examiner is invited to contact the undersigned at the below listed telephone number.

Respectfully Submitted,
Toshihide Kobayashi et al.



Bruce H. Bernstein
Reg. No. 29,027

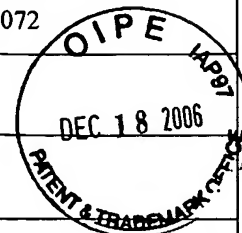
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FORM PTO-1449

U.S. Department of Commerce
Patent and Trademark OfficeAtty. Docket No.
P26337Application No.
10/516,072INFORMATION DISCLOSURE STATEMENT
BY APPLICANT

(Use several sheets if necessary)

Applicant
Toshihide Kobayashi et al.Filing Date
May 30, 2003Group
1655

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

1	L.F. AMOROSA et al., "The Effects of Polyoxyethylated Cholesterol Feeding on Hepatic Cholesterol Synthesis and Intestinal Cholesterol Absorption in Rats", Atherosclerosis, Vol. 64, pp. 117-123 (1987).
2	Hideki ISHIWATA et al., "Physical-Chemistry Characteristics and Biodistribution of Poly(ethylene glycol)-Coated Liposomes Using Poly(oxyethylene) Cholesteryl Ether", Chem. Pharm. Bull., Vol. 43, No. 6, pp1005-1011 (1995).
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4	Mark S. BRETSCHER et al., "Cholesterol and the Golgi Apparatus", Science, Vol. 261, pp. 1280-1281 (1993).
5	Anton RIETVELD et al., "The Differential Miscibility of Lipids as the Basis for the Formation of Functional Membrane Rafts", Biochimica et Biophysica Acta, Vol. 1376, pp. 467-479 (1998).
6	Rhoderick E. BROWN et al., "Sphingolipid Organization in Biomembranes: What Physical Studies of Model Membranes Reveal", Journal of Cell Science, Vol. 111, pp. 1-9 (1998).
7	Teymuraz V. KURZCHALIA et al., "Membrane Microdomains and Caveolae", Curr. Opin. Cell. Biol., Vol. 11, pp. 424-431 (1999).
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9	D.A. BROWN et al., "Functions of Lipid Rafts in Biological Membranes", Annu. Rev. Cell Dev. Biol., Vol. 14, pp. 111-136 (1998).
10	Kai SIMONS et al., "Lipid Rafts and Signal Transduction", Nature Reviews: Molecular Cell Biology", Vol. 1, pp. 31-41 (2000).
11	Linda J. PIKE et al., "Cholesterol Depletion Delocalizes Phosphatidylinositol Bisphosphate and Inhibits Hormone-Stimulated Phosphatidylinositol Turnover", The Journal of Biological Chemistry, Vol. 273, No. 35, pp. 22298-22304 (1998).
12	PRALLE et al., "Sphingolipid-Cholesterol Rafts Diffuse as Small Entities in the Plasma Membrane of Mammalian Cells", The Journal of Cell Biology, Vol. 148, No. 5, pp. 997-1007 (2000).
13	Katja RÖPER et al., "Retention of Prominin in Microvilli Reveals Distinct Cholesterol-Based Lipid Microdomains in the Apical Plasma Membrane", Nature Cell Biology, Vol. 2, pp. 582-592 (2000).
14	Michael S. BROWN et al., "A Proteolytic Pathway that Controls the Cholesterol Content of Membranes, Cells, and Blood", Proc. Natl. Acad. Sci. USA, Vol. 96 pp. 11041-11048 (1999).
15	Kai SIMONS et al., "How Cells Handle Cholesterol", Science, Vol. 290, pp. 1721-1726 (2000).
16	Yiannis A. IOANNOU, "Multidrug Permeases and Subcellular Cholesterol Transport", Nature Reviews: Molecular Cell Biology, Vol. 2, pp. 657-668 (2001)
17	Peter G. PENTCHEV et al., "The Niemann-Pick C Lesion and its Relationship to the Intracellular Distribution and Utilization of LDL Cholesterol", Biochimica et Biophysica Acta, Vol. 1225, pp. 235-243 (1994)

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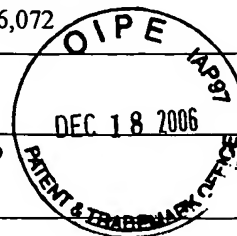
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FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	NO
.	8	- 1 3 1 1 9 7	11/25/97	JAPAN				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

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